restriction, Claims 1-16 and 39-42 were discussed, as well as a substantial number of citations. This discussion covered the 1980 paper by Muir describing many of the basic properties of nonlinear acoustic effects and his images of the 1st through the 5th harmonics of sonar transmissions. The contemporaneous papers by Muir and Carstensen (1980) and Carstensen, Law, McKay and Muir (1980) were discussed. The B/A parametric imaging patents of Nicolas and Pesque and the paper of Ichida (1983) were compared with the claims of the present invention. The transmission ultrasound experiments of Starritt with muscle (1985) and bovine liver (1986) were reviewed and the contrast agent papers by Schrope (1992 and 1993) were discussed. The identification of the target of a lithotripter or therapy device through detection of a harmonic of the lithotripsy or therapy pulse as shown in the two Umemura patents was reviewed, as well as the Fourier detection of the harmonic of the scalar quantity of a time domain signal as shown in the two Goh patents. The PCT application and corresponding paper of Christopher and the two papers of Ward (1995 and 1997) were discussed.

The present invention is directed to tissue harmonic imaging in which the same transducer is used for both transmission and reception in a pulse-echo mode of operation. This contrasts with most of the cited references, which are simply theoretical studies of sound propagation models and equations (e.g., Christopher) or use separate devices for transmission and reception (e.g., Muir, Starritt and Ward). In the latter cases, hydrophones are used for reception due to narrowband limitations of the transmitting device or to take advantage of the flat response characteristics of hydrophones. Most significantly, the references are devoid of actual experience with pulse-echo ultrasonic imaging of tissue. Most of the prior art experiments were in water, not tissue. Thus, the references do not recognize or solve the problem addressed by the present invention, multipath reverberation. (Starrett did experiments with muscle and liver tissue, but with a transmission-

type system in which, unlike pulse-echo systems, multipath reverberation problems do not arise.)

As many of the references suggest, and as explained at length in the present specification, tissue harmonic imaging offers the promise of improved resolution and reduced sidelobe clutter as compared with fundamental imaging. The improvement in resolution arises by virtue of the narrower main response lobe of the harmonic beam pattern as compared with that of the fundamental. Sidelobe clutter is reduced by virtue of the improved main lobe to sidelobe response ratio. But harmonic imaging imposes challenges as well as potential benefits. For one, the amplitudes of harmonic components will be well below those of the corresponding fundamental signals, requiring greater sensitivity as signal-to-noise ratios are poorer. For another, the higher frequency harmonic components are more susceptible to frequency dependent attenuation than are the lower frequency fundamental signals. These disadvantageous properties place an even higher premium on artifact elimination such as multipath reverberation artifacts addressed by the present invention.

The problem of multipath reverberation artifacts manifests itself in the wire phantom images shown in Fig. 13 of the 1997 Ward paper. As discussed in the paragraph spanning pages 151-52 of the Ward paper, these images are contaminated by vertical lines due to multiple reflections between the transducer and hydrophone, and by "ghost" images of the wires that are due to an extra reflection from the wires to the transducer. Such contaminating artifacts are unacceptable in medical images, and particularly in tissue harmonic images where sensitivity is critical. What is Ward's solution to this problem? "Ignore the various unwanted reflections...."

The problem is especially acute when actually imaging the body, since a number of potential sources of multipath reflection exist. The transmitted wave must pass through the skin, then fat, then muscle, then membranes such as the peritoneum or epicardium before arriving at an organ to be imaged. In the case of cardiac imaging the ribcage is a strong source of multipath reflections, as

the discussion of Figs. 2-3 of the specification makes clear. Thus, it is important to address the problem of multipath reverberation in order to produce acceptable tissue harmonic images.

The present inventors have recognized this problem, and have found that the buildup of harmonic signal content is slower in tissue than in the water medium used by most of the reference researchers. Taking advantage of this, the present inventors have used an array transducer to transmit wave components which, in the near field, are distributed over the elements of the array and at that point are of insufficient energy to stimulate a significant harmonic response in the near field. This prevents the rapid buildup of potential multipath-prone harmonics in the near field. But as the wave components transmitted by the elements of the array come into focus at a greater depth, the concentration of the acoustic energy increases, and the buildup of harmonics increases also. Thus, the developing harmonics are present at the focal region of the array transducer where harmonic echo returns are desired, but are greatly diminished in the near field where they could reflect from ribs and other tissue interfaces and cause multipath artifacts.

It may be appreciated that the elements of an array transducer, individually actuated as they are in timed sequence, distribute the transmitted energy both spatially and temporally in the near field just ahead of the array. A similar effect could be developed by use of a focusing lens in combination with a piston transducer, with the lens curvature controlling the time of emission of the transmitted wave across the surface of the lens. However, such a fixed focal arrangement would suffer from loss of the dynamic electronic focusing and steering capabilities provided by an array transducer. The claims of the present invention are restricted to the illustrated preferred embodiment which uses an array transducer and not a piston transducer with a focusing lens.

It is seen that the claimed invention solves the multipath reverberation problem found by Ward but unsolved by Ward. The

Christopher PCT patent and corresponding 1997 paper discuss phase aberration effects in the near field, and spend pages to show that, while the main lobe to sidelobe ratio is degraded by these effects, the ratio is still high enough to afford good sidelobe clutter rejection (see pg. 32 of the PCT application). But Christopher, being a study and not reporting experimental results like Ward, does not recognize the multipath problem or suggest its solution. As mentioned during the interview, applicants would be pleased to antedate the Ward and Christopher citations with a demonstration of their prior invention, but do not believe it is necessary to do so, since there is no teaching or suggestion of applicants' invention by these citations.

Turning now to the claims, it is seen that Claim 1 has been amended to be limited to tissue harmonic imaging. An array transducer is used for both transmission and reception (pulse-echo), and a transmit controller is operable to cause the array transducer to have the desired near field and focal depth transmission characteristics. Received echo signals are processed, and a circuit passes tissue harmonic signals to the exclusion of the fundamental frequency. An image processor forms a tissue harmonic image. As stated at the conclusion of the claim, multipath clutter in the tissue harmonic image is substantially reduced by this apparatus.

Other features of the invention of Claim 1 are recited in the dependent claims. Claim 5, for instance, specifies that the circuit which passes harmonic frequencies to the substantial exclusion of the fundamental frequencies also substantially excludes multipath clutter at the fundamental frequency. Claim 6 recites that this filter is a programmable digital filter. Claims 7 and 8 recite that the image processor comprises a B mode processor which includes an amplitude detector for detecting the envelope of harmonic echo signals.

Claim 11 is limited to a method of producing tissue harmonic images. The method begins with the transmission by an array transducer of fundamental frequency wave components from a

plurality of elements which spreads the transmitted energy over the plurality of elements in the near field. As the wave components converge to a focus the intensifying energy develops harmonic frequency components at greater depths. Harmonic echoes are received by the array transducer and used to form coherent echo signals. Harmonic components are passed to the exclusion of fundamental frequencies, and the tissue harmonic signals are processed to produce image signals for display. The method results in a substantial reduction of multipath clutter in the tissue harmonic ultrasonic image. In Claim 14 the passing of tissue harmonic signals is accomplished by filtering, which excludes fundamental frequencies and multipath clutter at the fundamental frequency. In Claim 15 the processing step comprises B mode processing and in Claim 16 the tissue harmonic signals are amplitude detected.

Claim 39 describes an ultrasonic diagnostic imaging system for performing tissue harmonic imaging. A transducer array transmits ultrasonic energy at a fundamental frequency which is less than or equal to 5 MHz and receives ultrasonic echoes from tissue at a harmonic which is less than or equal to 10 MHz. A transmit controller causes elements of the array to transmit wave components which are distributed over the array in the near field, and which become focused to develop harmonic frequency components at a focal depth. Received echo signals are digitized and a digital beamformer forms coherent echo signals. A filter passes tissue harmonic signals to the substantial exclusion of fundamental frequency signals and an image processor produces a tissue harmonic image. The multipath clutter of the tissue harmonic image is substantially reduced. In the dependent claims the transmit and harmonic frequencies are further restricted to 5 and 2.5 MHz, and to 4 and 2 MHz. In Claim 42 the filter is a programmable digital filter which substantially excludes fundamental frequency multipath clutter.

Two information disclosure statements are being delivered by hand concurrent with the facsimile filing of this voluntary

amendment to make of record the numerous patents and technical papers referred to above which were discussed during the telephonic interview.

In light of the foregoing amendment and remarks, it is respectfully submitted that Claims 1-16 and 39-42 as amended are patentable over all of the citations discussed during the interview and the additional citations of record in this case. Accordingly, it is respectfully that Claims 1-16 and 39-42 be allowed and this case passed on to issuance.

Respectfully submitted,

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August 25, 1998

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